

P. PENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

Date of mailing (day/month/year) 19 December 2000 (19.12.00)	From the INTERNATIONAL BUREAU To: BERESFORD, Keith, Denis, Lewis Beresford & Co. 2-5 Warwick Court High Holborn London WC1R 5DH ROYAUME-UNI
Applicant's or agent's file reference JAC/5282199	IMPORTANT NOTIFICATION
International application No. PCT/GB00/01728	International filing date (day/month/year) 05 May 2000 (05.05.00)

1. The following indications appeared on record concerning:				
<input type="checkbox"/> the applicant <input type="checkbox"/> the inventor <input checked="" type="checkbox"/> the agent <input type="checkbox"/> the common representative				
Name and Address BERESFORD, Keith, Denis, Lewis Beresford & Co. 2-5 Warwick Court High Holborn London WC1R 5DJ United Kingdom	State of Nationality		State of Residence	
	Telephone No.		0207 831 2290	
	Facsimile No.		0207 405 4092	
	Teleprinter No.			

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:				
<input type="checkbox"/> the person <input type="checkbox"/> the name <input checked="" type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence				
Name and Address BERESFORD, Keith, Denis, Lewis Beresford & Co. 2-5 Warwick Court High Holborn London WC1R 5DH United Kingdom	State of Nationality		State of Residence	
	Telephone No.		0207 831 2290	
	Facsimile No.		0207 405 4092	
	Teleprinter No.			

3. Further observations, if necessary:				

4. A copy of this notification has been sent to:				
<input checked="" type="checkbox"/> the receiving Office <input type="checkbox"/> the designated Offices concerned <input type="checkbox"/> the International Searching Authority <input checked="" type="checkbox"/> the elected Offices concerned <input checked="" type="checkbox"/> the International Preliminary Examining Authority <input type="checkbox"/> other:				

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Juan Cruz Telephone No.: (41-22) 338.83.38
---	---

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)Date of mailing (day/month/year)
17 January 2001 (17.01.01)

To:

BERESFORD, Keith, Denis, Lewis.
Beresford & Co.
2-5 Warwick Court
High Holborn
London WC1R 5DH
ROYAUME-UNIApplicant's or agent's file reference
JAC/5282199

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/01728International filing date (day/month/year)
05 May 2000 (05.05.00)

1. The following indications appeared on record concerning:

 the applicant the inventor the agent the common representative

Name and Address	State of Nationality	State of Residence
	GB	GB
	Telephone No.	
	Facsimile No.	
Teleprinter No.		

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

 the person the name the address the nationality the residence

Name and Address DAVIES DAVID NEVILLE C/O Electrosols Ltd Thursley_copse Farnham lane Haslemere Surrey GU27 1HA United Kingdom	State of Nationality	State of Residence
	GB	GB
	Telephone No.	
	Facsimile No.	
Teleprinter No.		

3. Further observations, if necessary:

The person in Box is added as applicant/inventor designated for the US.

4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Lazar Joseph Panakal Telephone No.: (41-22) 338.83.38
---	--

PENT COOPERATION TREA

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION
(PCT Rule 61.2)

Date of mailing (day/month/year) 19 December 2000 (19.12.00)	To: Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 Arlington, VA 22202 ETATS-UNIS D'AMERIQUE in its capacity as elected Office
---	---

International application No. PCT/GB00/01728	Applicant's or agent's file reference JAC/5282199
---	--

International filing date (day/month/year) 05 May 2000 (05.05.00)	Priority date (day/month/year) 06 May 1999 (06.05.99)
--	--

Applicant

COFFEE, Ronald, Alan et al

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

16 November 2000 (16.11.00)

in a notice effecting later election filed with the International Bureau on:

2. The election was was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Juan Cruz
---	-------------------------------------

Facsimile No.: (41-22) 740.14.35

Telephone No.: (41-22) 338.83.38

TENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference JAC/5282199	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 00/01728	International filing date (day/month/year) 05/05/2000	(Earliest) Priority Date (day/month/year) 06/05/1999
Applicant ELECTROSOLS LTD et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
 - contained in the international application in written form.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority in written form.
 - furnished subsequently to this Authority in computer readable form.
 - the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. Certain claims were found unsearchable (See Box I).

3. Unity of Invention is lacking (see Box II).

4. With regard to the title,

- the text is approved as submitted by the applicant.
- the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- the text is approved as submitted by the applicant.
- the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

- as suggested by the applicant.
- because the applicant failed to suggest a figure.
- because this figure better characterizes the invention.

2

None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 00/01728

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61J3/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61J A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 03267 A (ELECTROSOLS LTD ;COFFEE RONALD ALAN (GB)) 29 January 1998 (1998-01-29) cited in the application claims 1,31,32,37; figures ---	1-7, 9-25, 27-29, 33
Y	FR 2 335 206 A (HOFFMANN LA ROCHE) 15 July 1977 (1977-07-15)	1-7, 9-25, 27-29, 33
X	the whole document ---	30-32
X	US 5 229 164 A (PINS HEINRICH ET AL) 20 July 1993 (1993-07-20) the whole document ---	30-32
X	WO 90 06969 A (FUISZ PHARMACEUTICAL LTD) 28 June 1990 (1990-06-28) claims 47,48 ---	30-32
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

10 August 2000

Date of mailing of the international search report

18/08/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Godot, T

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 00/01728

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 019 929 A (DUDZIK JOACHIM ;DUDZIK WINFRIED (DE)) 10 December 1980 (1980-12-10) abstract -----	30-32

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/01728

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9803267	A	29-01-1998	AU 3628497 A		10-02-1998
			EP 0912251 A		06-05-1999
FR 2335206	A	15-07-1977	US 4029758 A		14-06-1977
			US 4029757 A		14-06-1977
			US 4031200 A		21-06-1977
			AT 365449 B		11-01-1982
			AT 923976 A		15-06-1981
			CA 1085295 A		09-09-1980
			CH 624846 A		31-08-1981
			DE 2656387 A		30-06-1977
			DK 562276 A, B,		16-06-1977
			FI 763597 A, B,		16-06-1977
			GB 1561100 A		13-02-1980
			GR 81307 A		11-12-1984
			IL 51096 A		16-09-1980
			JP 1395182 C		11-08-1987
			JP 52076419 A		27-06-1977
			JP 62000125 B		06-01-1987
			LU 76378 A		18-01-1978
			MC 1117 A		12-08-1977
			NL 7613922 A, B,		17-06-1977
			NO 764242 A, B,		16-06-1977
			NZ 182871 A		25-10-1979
			PH 14489 A		07-08-1981
			PT 65960 A, B		01-01-1977
			SE 438597 B		29-04-1985
			SE 7614123 A		25-08-1977
			US 4072551 A		07-02-1978
			US 4126502 A		21-11-1978
			ZA 7607136 A		26-10-1977
			PH 13712 A		09-09-1980
			US 4126503 A		21-11-1978
			AU 2051976 A		22-06-1978
			ES 454207 A		16-03-1978
			PH 13423 A		23-04-1980
			US 4083741 A		11-04-1978
			PH 16921 A		12-04-1984
			PH 12959 A		19-10-1979
			US 4307555 A		29-12-1981
			US 4349531 A		14-09-1982
			PH 13426 A		23-04-1980
			US 4165998 A		28-08-1979
			PH 17318 A		20-07-1984
			US 4069084 A		17-01-1978
			PH 12825 A		31-08-1979
			US 4069086 A		17-01-1978
			AU 514195 B		29-01-1981
			BE 849377 A		14-06-1977
			CA 1087974 A		21-10-1980
			PH 13279 A		27-02-1980
			PH 16400 A		22-09-1983
			US 4128445 A		05-12-1978
US 5229164	A	20-07-1993	DE 3545090 C		25-06-1987
			AT 62406 T		15-04-1991
			AU 577213 B		15-09-1988
			AU 6841687 A		15-07-1987

INTERNATIONAL SEARCH REPORT

Information on patent family members

National Application No

PCT/GB 00/01728

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 5229164	A	CA 1289074 A DE 3678719 D DK 396787 A, B, WO 8703805 A EP 0227050 A EP 0250578 A GR 3002266 T JP 7078018 B JP 63502430 T NO 175038 B		17-09-1991 16-05-1991 29-07-1987 02-07-1987 01-07-1987 07-01-1988 30-12-1992 23-08-1995 14-09-1988 16-05-1994
WO 9006969	A 28-06-1990	US 5011532 A AT 136735 T AU 645248 B AU 4814690 A BR 8907819 A CA 2005200 A DE 68926307 D EP 0448626 A EP 0687498 A HU 58774 A HU 217035 B IL 92462 A JP 4502492 T KR 157626 B US 5370881 A US 5034421 A US 5028632 A US 5096492 A ZA 8909318 A		30-04-1991 15-05-1996 13-01-1994 10-07-1990 12-11-1991 13-06-1990 23-05-1996 02-10-1991 20-12-1995 30-03-1992 29-11-1999 30-05-1994 07-05-1992 01-12-1998 06-12-1994 23-07-1991 02-07-1991 17-03-1992 26-09-1990
EP 0019929	A 10-12-1980	DE 2922522 A DE 3042916 A JP 55163175 A		04-12-1980 01-07-1982 18-12-1980

PENT COOPERATION TREATY

PCT

REC'D 22 AUG 2001
14

WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JAC/5282199	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/01728	International filing date (day/month/year) 05/05/2000	Priority date (day/month/year) 06/05/1999	
International Patent Classification (IPC) or national classification and IPC A61J3/00			

Applicant

ELECTROSOLS LTD et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 16/11/2000	Date of completion of this report 20.08.01
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Spyropoulou, E Telephone No. +49 89 2399 2843



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/01728

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-25 as originally filed

Claims, No.:

1-33 as received on 10/05/2001 with letter of 10/05/2001

Drawings, sheets:

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/01728

the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-28,33

No: Claims 29-32

Inventive step (IS) Yes: Claims 1-28,33

No: Claims 29-32

Industrial applicability (IA) Yes: Claims 1-33

No: Claims

2. Citations and explanations *see separate sheet*

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/01728

V.

- 1). a). From US-A-5229164 (D1), see col.10 examples 1, 4 and 5 from WO-A-90/06969 (D2), see claims 47-49 and DE-A-0019929 (D3), see claims 1 and 3, a consumable or dissolvable tablet comprising a web of fibres of a biodissolvable carrier material (gelatin) carrying at least one active ingredient, the tablet being arranged to dissolve or disintegrate in a wet environment such as a tongue or a mouth.
- b). Claims 29-31 are drafted as a product-by-process claim. Claims for products defined in terms of a process of manufacture are new and inventive only if the products as such are new and inventive. A product is not rendered novel merely by the fact that it is produced by means of a new process.

There are only two basic kinds of claim, viz, claims to a physical entity (product, apparatus) and claims to an activity (process, use) (see PCT Preliminary Examination Guidelines III 3.1). In order for a claim to be clear its wording should leave no doubt as to its category (PCT/GL III 4.1).

In the present case a consumable or dissolvable tablet comprising a web of fibres of a biodissolvable carrier material (gelatin) carrying at least one active ingredient, the tablet being arranged to dissolve or disintegrate in a wet environment such as a tongue or a mouth as defined in said claims 29-31 manufactured using the method according to claims 1 to 16 does not differ from the consumable or dissolvable tablets known from the prior art disclosed in D1, D2 and D3.

Consequently the tablet according to claims 29-32 of the present application is known from D1, D2 and D3 and therefore not novel.

- 2). The method of manufacturing consumable or dissolvable tablets according to claims 1, 3 and 10 and an apparatus for manufacturing said tablets according to claims 17 and 19 differ from the disclosure of D1 in that a liquid containing a biodissolvable carrier is supplied to an outlet, an electric field is established between the outlet and a

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/01728

support surface to cause the liquid to form a fibre mat and the web or mat is separated into a plurality of individual tablets.

From WO-A-98/03267 (D4), the use of electrohydrodynamic comminution to produce fibre, fibrils, or fibre segments, droplets or particles and a method of manufacturing a mat of fibre fragments or particles are known, see D4 claims 1, 9, 37 and description page 2, second paragraph, according to which a liquid containing a biodissolvable carrier is supplied to an outlet, an electric field is established between the outlet and a support surface to cause the liquid to form a fibre mat (see D4, claims 1, 2 and 26).

The method defined in claims 1, 3 and 10 of the present application differs from the method disclosed in D4 in that the mat or web of fibres is separated into a plurality of individual tablets.

D4 is concerned primarily with forming wound dressings or coverage which are intended to provide good coverage over the wound while allowing controlled release of a substance contained within the fibres.

No suggestion has been made in D4 that a consumable or dissolvable tablet can be formed from the fibre mats.

The subject matter of claims 1,3,10,17,19 and 33 is therefore novel and involves an inventive step.

VIII.

Although claims 1, 3,10 and 17,19 and 29, 30, 31 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness.

Hence, claims 1, 3,10 and 17,19 and 29,30, 31 do not meet the requirements of Article 6 PCT.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/01728

VII.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D4 is not mentioned in the description, nor are these documents identified therein.

replaced by
prior 634

WO 00/67694

PCT/GB00/01728

26

CLAIMS:

1. A method of manufacturing consumable or dissolvable tablets, comprising:
 - 5 supplying a liquid containing a biodissolvable carrier to an outlet;
 - establishing an electric field between the outlet and a support surface to cause liquid issuing from the outlet to form at least one fibre or fibrils of the biodissolvable carrier which fibre or fibrils deposit(s) onto the surface to form a fibre web or mat;
 - 10 separating the web or mat into a plurality of individual tablets; and
 - incorporating at least one active ingredient in
 - 15 and/or the tablets.
2. A method according to claim 1, which comprising:
 - separating the web or mat into a plurality of individual tablets by cutting the web or mat.
- 20 3. A method of manufacturing tablets, comprising:
 - supplying to an outlet a liquid containing a hydrophilic biologically compatible carrier which melts or liquifies on contact with a wet surface;
 - 25 establishing an electric field between the outlet and a support surface to cause liquid issuing from the outlet to form at least one fibre or fibrils of the carrier;

WO 00/67694

27

causing the at least one fibre or fibrils to deposit onto the surface to form a plurality of individual tablets each comprising a fibre web or mat; and providing the tablets with at least one active ingredient.

5

4. A method according to any one of the proceeding claims, which comprises supplying to provide the liquid a composition comprising at least one of a gelatin, polyvinyl pyridine, polyvinyl alcohol, poly-sucrose, starch, cellulose, a cellulose derivative, a sugar, a confectionary product such as toffee or caramel.

10

5. A method according to any one of claims 1 to 3, which comprises supplying as the liquid a solution consisting essentially of 5 grams of fish gelatin in a solvent consisting of from 7 to 9 millilitres of water and 10 to 11 millilitres of ethanol.

15

20 6. A method according to any one of claims 1 to 3, which comprises supplying as the liquid a solution consisting essentially of 5 grams of fish gelatin in a solvent consisting of 8 millilitres of water, 10 millilitres of ethanol and 1 millilitre of peppermint flavouring.

25

7. A method according to any one of the preceding claims, which comprising providing an air flow to

encourage the deposition of the at least one fibre or fibrils on the surface.

8. A method according to any one of the preceding
5 claims, which further comprises regulating the temperature, for example by applying heat, of the region where the liquid issues from the outlet to facilitate the formation of the at least one fibre or fibrils.

10 9. A method according to any one of the preceding claims, which comprises establishing the electric field by applying a high voltage to the surface.

10. A method of manufacturing tablets, comprising:
15 supplying a liquid consisting essentially of a hydrophilic solution of gelatin to an outlet;
establishing an electric field between the outlet and a support surface to cause liquid issuing from the outlet to form on the surface a web or mat consisting of
20 at least one gelatin fibre or gelatin fibrils;

separating the web or mat into a plurality of individual tablets; and

incorporating at least one active ingredient and a sweetener such as saccharine into and/or on the tablets.

25 11. A method according to any one of the preceding claims, which comprises using as the surface a rotatable endless surface such as a belt.

12. A method according to any one of the preceding claims, which comprises incorporating the at least one active ingredient by spraying the active ingredient onto at least one of: the at least one fibre or fibrils; 5 the mat or web; and the individual tablets.

13. A method according to any one of the preceding claims, which comprises incorporating the active ingredient into the at least one fibre or fibrils.

10

14. A method according to any one of the preceding claims, which comprises forming the at least one fibre or fibrils with a core containing an active ingredient.

15

15. A method of manufacturing a pharmaceutical product which comprises using a method in accordance with any one of the preceding claims and providing as the at least one active ingredient an ingredient which is pharmacologically or biologically active.

20

16. A method of manufacturing a confectionary product which comprises using a method in accordance with any one of claims 1 to 14 to form a plurality of individual tablets and incorporating as the at least one active 25 ingredient at least one of the following: sugar; chocolate; a flavouring; and a colorant.

17. Apparatus for manufacturing consumable or dissolvable tablets, comprising:

means for supplying a liquid containing a biodissolvable carrier to an outlet;

5 means for establishing an electric field between the outlet and a support to cause liquid issuing from the outlet to form at least one fibre or fibrils of the biodissolvable carrier which deposit(s) onto the support to form a fibre web or mat;

means for separating the web or mat into a plurality of individual tablets; and

10 means for incorporating at least one active ingredient in the tablet.

18. Apparatus according to claim 15, wherein the separating means comprises at least one cutter.

15

19. Apparatus for manufacturing consumable or dissolvable tablets, comprising:

means for supplying a liquid containing a biodissolvable carrier to an outlet;

20 means for establishing an electric field between the outlet and a support to cause liquid issuing from the outlet to form at least one fibre or fibrils of the biodissolvable carrier;

25 means for causing the fibre or fibrils to deposit onto the support to form a plurality of individual tablets each comprising a fibre web or mat; and

means for incorporating at least one active ingredient into the web or mat.

20. Apparatus according to claim 17, 18 or 19, further comprising, for providing the liquid, a supply of a gelatin, polyvinyl pyridine, polyvinyl alcohol, polysucrose, starch, cellulose, a cellulose derivative, a sugar, a confectionary product such as toffee or caramel.

21. Apparatus according to any one of claims 17 to 19, further comprising, as the liquid, a supply of a solution consisting essentially of 5 grams of gelatin in 7 to 9 millilitres of water and 10 to 11 millilitres of ethanol.

22. Apparatus according to any one of claims 17 to 19, further comprising, as the liquid, a supply of a solution consisting essentially of 5 grams of gelatin in 8 millilitres of water, 10 millilitres of ethanol and 1 millilitre of peppermint flavouring.

23. Apparatus according to any one of claims 17 to 22, further comprising air flow causing means for facilitating the deposition of the at least one fibre or fibrils onto the support.

24. Apparatus according to any one of claims 17 to 23, wherein the electric field establishing means comprises means for applying a positive potential to the support.

25. Apparatus according to any one of claims 17 to 24, further comprising a rotatable endless surface as the support.

26. Apparatus according to any one of claims 17 to 25, further comprising an environmental control means for regulating the temperature of the region where liquid issues from the outlet.

5

27. Apparatus according to any one of claims 17 to 26, further comprising spraying means for spraying the at least one active ingredient onto at least one of: the fibre or fibrils; the mat or web; and individual tablets.

10

28. Apparatus according to any one of claims 17 to 27, further comprising means for supplying the active ingredient so that the at least one fibre or fibrils have a core containing the active ingredient.

15

29. A consumable or dissolvable tablet, pad or mat manufactured using a method in accordance with any one of claims 1 to 16 or apparatus in accordance with any one of claims 17 to 28.

20

30. A consumable or dissolvable tablet comprising a web of fibres of a biodissolvable carrier material carrying at least one active ingredient, the carrier material being arranged to dissolve or disintegrate in a wet environment such as on the tongue or in the mouth of a human being or other animal.

31. A consumable or dissolvable tablet comprising a web of fibres or fibrils of gelatin carrying at least one

active ingredient, the tablet being arranged to dissolve or disintegrate in a wet environment such as on the tongue or in the mouth of a human being or other animal.

5 32. A tablet according to claims 29, 30 or 31, wherein the active ingredient comprises a pharmacologically or biologically active ingredient.

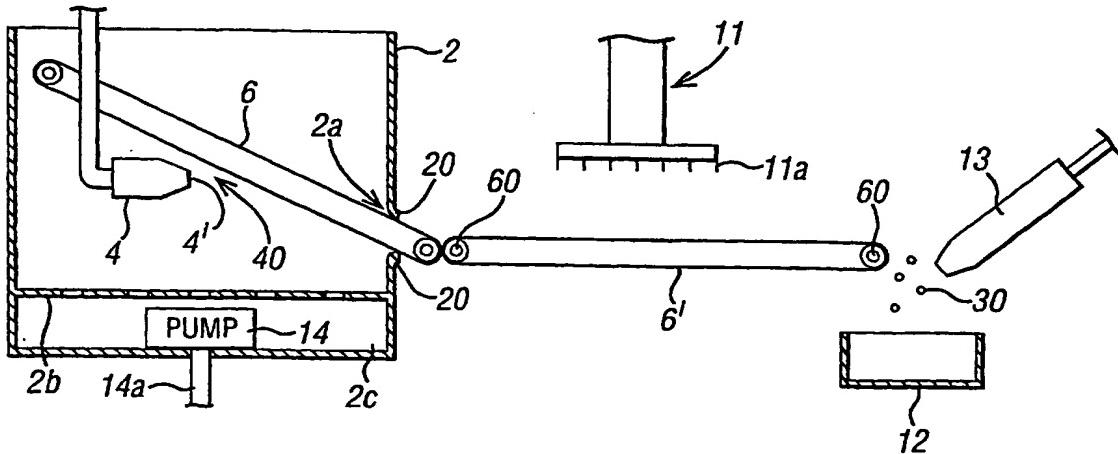
10 33. Use of electrohydrodynamic comminution to produce a consumable or dissolvable tablet.



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ :	A1	(11) International Publication Number:	WO 00/67694
A61J 3/00		(43) International Publication Date:	16 November 2000 (16.11.00)
(21) International Application Number:	PCT/GB00/01728	(81) Designated States:	AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date:	5 May 2000 (05.05.00)	(30) Priority Data:	9910505.8 6 May 1999 (06.05.99) GB
(71) Applicant (<i>for all designated States except US</i>): ELEC-TROSOLS LTD. [GB/GB]; Thursley Copse, Farnham Lane, Haslemere, Surrey GU27 1HA (GB).		(72) Inventors; and	
(73) Inventors/Applicants (<i>for US only</i>): COFFEE, Ronald, Alan [GB/GB]; Longdene House, Haslemere, Surrey GU27 2PH (GB). PIRRIE, Alastair, Bruce [GB/GB]; 91 Plantation Road, Oxford OX2 6JE (GB).		(74) Agents:	BERESFORD, Keith, Denis, Lewis et al.; Beresford & Co., 2-5 Warwick Court, High Holborn, London WC1R 5DJ (GB).

(54) Title: A METHOD AND APPARATUS FOR MANUFACTURING DISSOLVABLE TABLETS



Consumable or dissolvable tablets are manufactured by: supplying a liquid containing a biodissolvable carrier to an outlet (41); establishing an electric field between the outlet (41) and a support surface (6) to cause liquid issuing from the outlet to form at least one fibre or fibrils of the biodissolvable carrier which fibre or fibrils deposit(s) onto the surface to form a fibre web or mat; separating the web or mat into a plurality of individual tablets; and incorporating at least one active ingredient on or in the tablets.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 00/01728

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61J3/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61J A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 03267 A (ELECTROSOLS LTD ;COFFEE RONALD ALAN (GB)) 29 January 1998 (1998-01-29) cited in the application claims 1,31,32,37; figures	1-7, 9-25, 27-29,33
Y	FR 2 335 206 A (HOFFMANN LA ROCHE) 15 July 1977 (1977-07-15)	1-7, 9-25, 27-29,33
X	the whole document ---	30-32
X	US 5 229 164 A (PINS HEINRICH ET AL) 20 July 1993 (1993-07-20) the whole document	30-32
X	WO 90 06969 A (FUISZ PHARMACEUTICAL LTD) 28 June 1990 (1990-06-28) claims 47,48 ---	30-32
	-/-	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

10 August 2000

18/08/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Godot, T

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/01728

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 019 929 A (DUDZIK JOACHIM ; DUDZIK WINFRIED (DE)) 10 December 1980 (1980-12-10) abstract -----	30-32

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte...inal Application No

PCT/GB 00/01728

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9803267	A 29-01-1998	AU 3628497 A		10-02-1998
		EP 0912251 A		06-05-1999
FR 2335206	A 15-07-1977	US 4029758 A		14-06-1977
		US 4029757 A		14-06-1977
		US 4031200 A		21-06-1977
		AT 365449 B		11-01-1982
		AT 923976 A		15-06-1981
		CA 1085295 A		09-09-1980
		CH 624846 A		31-08-1981
		DE 2656387 A		30-06-1977
		DK 562276 A,B,		16-06-1977
		FI 763597 A,B,		16-06-1977
		GB 1561100 A		13-02-1980
		GR 81307 A		11-12-1984
		IL 51096 A		16-09-1980
		JP 1395182 C		11-08-1987
		JP 52076419 A		27-06-1977
		JP 62000125 B		06-01-1987
		LU 76378 A		18-01-1978
		MC 1117 A		12-08-1977
		NL 7613922 A,B,		17-06-1977
		NO 764242 A,B,		16-06-1977
		NZ 182871 A		25-10-1979
		PH 14489 A		07-08-1981
		PT 65960 A,B		01-01-1977
		SE 438597 B		29-04-1985
		SE 7614123 A		25-08-1977
		US 4072551 A		07-02-1978
		US 4126502 A		21-11-1978
		ZA 7607136 A		26-10-1977
		PH 13712 A		09-09-1980
		US 4126503 A		21-11-1978
		AU 2051976 A		22-06-1978
		ES 454207 A		16-03-1978
		PH 13423 A		23-04-1980
		US 4083741 A		11-04-1978
		PH 16921 A		12-04-1984
		PH 12959 A		19-10-1979
		US 4307555 A		29-12-1981
		US 4349531 A		14-09-1982
		PH 13426 A		23-04-1980
		US 4165998 A		28-08-1979
		PH 17318 A		20-07-1984
		US 4069084 A		17-01-1978
		PH 12825 A		31-08-1979
		US 4069086 A		17-01-1978
		AU 514195 B		29-01-1981
		BE 849377 A		14-06-1977
		CA 1087974 A		21-10-1980
		PH 13279 A		27-02-1980
		PH 16400 A		22-09-1983
		US 4128445 A		05-12-1978
US 5229164	A 20-07-1993	DE 3545090 C		25-06-1987
		AT 62406 T		15-04-1991
		AU 577213 B		15-09-1988
		AU 6841687 A		15-07-1987

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/01728

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 5229164	A	CA	1289074 A	17-09-1991
		DE	3678719 D	16-05-1991
		DK	396787 A, B,	29-07-1987
		WO	8703805 A	02-07-1987
		EP	0227050 A	01-07-1987
		EP	0250578 A	07-01-1988
		GR	3002266 T	30-12-1992
		JP	7078018 B	23-08-1995
		JP	63502430 T	14-09-1988
		NO	175038 B	16-05-1994
WO 9006969	A 28-06-1990	US	5011532 A	30-04-1991
		AT	136735 T	15-05-1996
		AU	645248 B	13-01-1994
		AU	4814690 A	10-07-1990
		BR	8907819 A	12-11-1991
		CA	2005200 A	13-06-1990
		DE	68926307 D	23-05-1996
		EP	0448626 A	02-10-1991
		EP	0687498 A	20-12-1995
		HU	58774 A	30-03-1992
		HU	217035 B	29-11-1999
		IL	92462 A	30-05-1994
		JP	4502492 T	07-05-1992
		KR	157626 B	01-12-1998
		US	5370881 A	06-12-1994
		US	5034421 A	23-07-1991
		US	5028632 A	02-07-1991
		US	5096492 A	17-03-1992
		ZA	8909318 A	26-09-1990
EP 0019929	A 10-12-1980	DE	2922522 A	04-12-1980
		DE	3042916 A	01-07-1982
		JP	55163175 A	18-12-1980

PATENT COOPERATION TREATY

RECEIVED

16 AUG 2000

BERESFORD & Co

PCT

From the INTERNATIONAL SEARCHING AUTHORITY

To:
BERESFORD & CO
 Attn. BERESFOERD, K.
 2-5 Warwick Court
 High Holborn
 London WC1R 5DJ
 UNITED KINGDOM

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

18/08/2000

Applicant's or agent's file reference
JAC/5282199

FOR FURTHER ACTION: See paragraphs 1 and 4 below

International application No.
PCT/GB 00/ 01728International filing date
(day/month/year)

05/05/2000

Applicant

ELECTROSOLS LTD et al.

1. The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Further action(s): The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority

 European Patent Office, P.B. 5818 Patentlaan 2
 NL-2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer
Robert Berends

Entered By: *an*
 Date: *30/8/2000*
 Bring Up: *23/8/2000*
 15/9/2000

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the International application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.